IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor: Tarak D. Mody

Froup Art Unit: 163

Serial Number: 10/659,499
Filing Date: September:

September 10, 2003

CONFIRMATION NO. 350

Title: Novel Metallotexaphyrin Derivatives

Certificate of Electronic Filing

I hereby certify that the attached Supplemental Information Disclosure Statement and all marked attachments are being deposited by Electronic Filing on August 20, 2006 by using the EFS – Web patent filing system and addressed to: Commissioner for Patents, P.O. Box 1450, Alexadria: VA 2313-1450.

By: Our Sugas

Date august 30,200

Commissioner for Patents P.O. Box 1450 Alexandria VA 22313-1450

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §1.97

Sir:

Applicant hereby submits an Information Disclosure Statement along with attached form PTO/SB/08. A copy of each listed publication is submitted, if required, pursuant to 37 CFR §§1.97-1.98, as indicated below.

Applicant respectfully requests that the listed information be considered by the Examiner and be made of record in the above-identified application. Applicant further requests that the Examiner initial and return the attached form PTO/SB/08 in accordance with MPEP \$699.

Applicant reserves the right to establish the patentiability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

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This statement is not intended to represent that a search has been made or that the information cited in the statement is, or is considered to be, prior art or material to natentability as defined in \$1.56. A.

37 CFR §1.97(b). This Information Disclosure Statement should be considered by the Office because: (1) It is being filed within 3 months of the filing date of a national application and is other than a continued prosecution application under \$1.53(d); (2) It is being filed within 3 months of entry of the national stage as set forth in §1.491 in an international application: -- OR --(3) It is being filed before the mailing of a first Office action on the merits: -- OR --(4) It is being filed before the mailing of a first Office action after the filing of a request for continued examination under \$1.114. B. \(\simeg 37 CFR \)\(\sigma 1.97(c)\). Although this Information Disclosure Statement is being filed after the period specified in 37 CFR \$1.97(b), above, it is filed before the mailing date of the earlier of (1) a final office action under §1.113, (2) a notice of allowance under §1.311, or (3) an action that otherwise closes prosecution on the merits, this Information Disclosure Statement should be considered because it is accompanied by one of: a statement as specified in \$1.97(e) provided concurrently herewith: -- OR -- \boxtimes a fee of \$180.00 as set forth in §1.17(p) authorized below, enclosed, or included with the payment of other papers filed together with this statement. C.

37 CFR \$1.97(d). Although this Information Disclosure Statement is being filed after the mailing. date of the earlier of (1) a final office action under \$1.113 or (2) a notice of allowance under \$1.311 it is being filed before payment of the issue fee and should be considered because it is accompanied by: i. a statement as specified in \$1.97(e): -- AND -ii. a fee of \$180.00 as set forth in §1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this Statement. D.

37 CFR \$1.97(e). Statement. A statement is provided herewith to satisfy the requirement under 37 CFR §§1,97(c): - AND/OR -A statement is provided herewith to satisfy the requirement under 37 CFR §§1.97(d): - AND/OR --A copy of a dated communication from a foreign patent office clearly showing that the

provided for under MPEP 609.04(b) V

information disclosure statement is being submitted within 3 months of the filing date on the communication is provided in lieu of a statement under 37 C.F.R. § 1.97(e)(1) as

| E. | disclosure application prior to the requirement | ent Onder 3 C.F.R. § 1704QL. Each neem of morntanion contained in the information statement was first cited in a communication from a forcein partent office in a counterpart that was received by an individual designated in § 1.56(c) not more than <u>thirty (30) days</u> felling of this information disclosure statement. This statement is made pursuant to the tst of 37 C.F.R. § 1.704(d) to avoid reduction of the period of adjustment of the patient term migh delay. | | | | |
|----|---|--|--|--|--|--|
| F. | F. \(\simeg \) 37 CFR \(\sigma 1.98(a)(2)\). The content of the Information Disclosure Statement is as follow | | | | | |
| | | Copies of each of the references listed on the attached Form PTO/SB/08 are enclosed herewith. | | | | |
| | | OR | | | | |
| | | Copies of U.S. Patent Documents (issued patents and patent publications) listed on the attached Form PTO/SB/08 are NOT enclosed. | | | | |
| | | - AND/OR - | | | | |
| | ☒ | Copies of Foreign Patent Documents and/or Non Patent Literature Documents listed on the attached Form PTO/SB/08 are enclosed in accordance with 37 CFR §1.98 (a)(2). | | | | |
| | | - AND/OR | | | | |
| | | Copies of pending unpublished U.S. patent applications are enclosed in accordance with 37 CFR §1.98(a)(2)(iii). | | | | |
| G. | ☐ 37 CF. references. | R §1.98(a)(3). The Information Disclosure Statement includes non-English patents and/or | | | | |
| | | Pursuant to 37 CFR §1.98(a)(3)(i), a concise explanation of the relevance of each patent, publication or other information provided that is not in English is provided herewith. | | | | |
| | | Pursuant to MPEP 609(B), an English language copy of a foreign search report is submitted herewith to satisfy the requirement for a concise explanation where non-English language information is cited in the search report. | | | | |
| | | OR | | | | |
| | | A concise explanation of the relevance of each patent, publication or other information provided that is not in English is as follows: | | | | |
| | | Pursuant to 37 CFR §1.98(a)(3)(ii), a copy of a translation, or a portion thereof, of the non-English language reference(s) is provided herewith. | | | | |
| H. | | $R \ \S 1.98(d)$. Copies of patents, publications and pending U.S. patent applications, or other a specified in 37 C.F.R. $\S 1.98(a)$ are not provided herewith because: | | | | |
| | | Pursuant to 37 CFR §1.98(d)(1) the information was previously submitted in an Information Disclosure Statement for another application under which this application claims priority for an earlier effective filing date under 35 U.S.C. 120. | | | | |
| | | Application in which the information was submitted: | | | | |
| | | Information Disclosure Statement(s) filed on: | | | | |
| | _ | AND | | | | |
| | | The information disclosure statement submitted in the earlier application complied with paragraphs (a) through (c) of $37 \text{CFR} \$1.98$. | | | | |

 \(\sum_{en} \) Fee Authorization. The Commissioner is hereby authorized to charge the above-referenced fees of \$50.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 23-2415 (Decket No.25922-702.501).

Respectfully submitted,

Reg. No. 47,664

WILSON SONSINI GOODRICH & ROSATI

Daled: August 30, 2006

By: Michael Hosterlar Ph.D.

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PTQ/SB/08 (07/05)

Approved for use through 07/31/2006. OMB 0651-0031
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| Substitute for form 1449/PTO INFORMATION DISCLOSURE | | | | Complete if Known | | |
|---|---|----|----------|------------------------|---------------|--|
| | | | | Application Number | 10/659,499 | |
| | | | | Filing Date | 09/10/2003 | |
| STATEMENT BY APPLICANT (Use as many sheets as necessary) | | | LICANT | First Named Inventor | Tarak D. Mody | |
| | | | cessary) | Art Unit | 1624 | |
| | | | | Examiner Name | Paul V. Ward | |
| Sheet | 1 | Of | 1 | Attorney Docket Number | 25922-702.501 | |

| | | FOREIGN | PATENT DO | CUMENTS | | | | |
|---|-------------------------|---|--------------------------------|--|---|---|--|--|
| Examiner Initials* | Cite No ³ | Foreign Patent Document Country Code* - Number* - Kind Code* (§* known) | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passagus or Relevant Figures Appear | | | |
| | 1. | WO-2002-39953 A2 | 23-05-2002 | Pharmacyclics, Inc. | | T | | |
| | 2. | WO-2002-17908 A1 | 07-03-2002 | Pharmacyclics, Inc. | | t | | |
| | 3. | WO-2002-039953 A3 | 23-05-2002 | Pharmacyclics, Inc. | | t | | |
| | | NON PATENT | LITERATUR | E DOCUMENTS | | 1 | | |
| xaminer Cite Include name of the author (in CAPITAL LETTERS), tide of the article (when appropriate item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issu nitials* No. | | | | | ppropriate), title of the clume-issue number(s), | | | |
| | 4. | BERNHARD, E.J. et al., "Re Radiosensitizing Agent," Ca | | | in as a | | | |
| | 5. | ROSENTHAL, D.I. et al., "A Phase I Single-Dose Trial of Gadolinium Texaphyrin (Gd-Tex), a Tumor Selective Radiation Sensitizer Detectable by Magnetic Resonance Imaging," Clinical Cancer Res. 5:739-745 (1999) | | | | | | |
| | 6. | SYNYTSYA, A. et al., "Interaction of metallotexaphyrins with mono- and polysaccharides," J. CHem. Soc., Perking Trans. 2:1876-1884 (2000) + Abstract from CAPLUS | | | | | | |
| | 7. | VIALA, J. et al., "Phases 1B Radiation Sensitizer Detectal Mctastases," Radiology 212: | ble at MR Imag | ging: Preliminary Results | exaphyrin, a in Brain | | | |

| Examiner | Date | |
|--|-----------------------|--|
| Signature | Considered | |
| *EXAMINER: Initial if reference considered, whether or not clusters is in conformance with MPEP of | Draw line through | citation if not in conformance and not considered. Include conv. |
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